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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,607	08/16/2006	Hitoshi Matsubara	47233-5006	2679

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DRINKER BIDDLE & REATH (DC)
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WASHINGTON, DC 20005-1209

EXAMINER

SCHMIDTMANN, BAHAR

ART UNIT	PAPER NUMBER
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1623

NOTIFICATION DATE	DELIVERY MODE
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06/23/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DBRIPDocket@dbr.com
penelope.mongelluzzo@dbr.com

Office Action Summary	Application No. 10/589,607	Applicant(s) MATSUBARA ET AL.	
	Examiner BAHAR SCHMIDTMANN	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 20-50 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action details a Restriction Requirement due to a Lack of Unity.

Status of the Claims/Priority

This application is a 35 U.S.C. § 371 National Stage Filing of International Application No. PCT/JP05/02411, filed 17 February 2005, which claims foreign priority under 35 U.S.C. §119(a-d) to JP 2004-40679, filed 17 February 2004.

Unity of Invention

A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. For example, a corresponding technical feature is exemplified by a key defined by certain claimed structural characteristics which correspond to the claimed features of a lock to be used with the claimed key.

A process is "specially adapted" for the manufacture of a product if the claimed process inherently produces the claimed product with the technical relationship being present between the claimed process and the claimed product. The expression "specially adapted" does not imply that the product could not also be manufactured by a different process.

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As set forth in Rule 13.1 of the Patent Cooperation Treaty (PCT), the international application shall relate to one invention only or to a group of inventions. Moreover, as stated in PCT Rule 13.2, the requirement of unity of invention referred to in PCT Rule 13.1 shall be fulfilled where a group of inventions is claimed in one and the same international application only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression special technical features shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art, so linked, as to form a general inventive concept.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

When Claims Are Directed to Multiple Categories of Inventions: As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; or (2) A product and process of use of said product; or (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) A process and an apparatus or means specifically designed for carrying out the said process; or (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means

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specifically designed for carrying out the said process. Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

Restrictions Requirement

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claim(s) 20-27 and 34-45, drawn to a composition comprising polymerized and non-polymerized catechins, wherein the content of the polymerized catechins is higher than that of the non-polymerized catechins
- II. Claim(s) 28-33, drawn to a method for producing a composition in which the ratio of the polymerized catechins to the non-polymerized catechins is made higher than in the original aqueous liquid, which comprises the steps of contacting the aqueous liquid with an adsorbent while the liquid is held to a temperature of at least 50 °C, whereby the non-polymerized catechins is selectively removed.
- III. Claim(s) 46-50, drawn to a method comprising administering a compound which contains polymerized catechins and non-polymerized catechins, wherein the content of the polymerized catechins is higher than that of the non-polymerized catechins

The technical feature among all groups is “a composition comprising polymerized and non-polymerized catechins, wherein the content of the polymerized catechins is higher than that of the non-polymerized catechins”. The inventions listed as Groups I - III do not relate to a single general inventive concept under PCT Rule 13.1 because,

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under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Ikeura et al. (Anti-adipogenic effect of cocoa --- *In vitro* experiment of lipase inhibitory effect, published 2003; cited by Applicant in Information Disclosure Statement) teaches cocoa, green tea and oolong tea were subjected to an ethanol extraction procedure followed by ODS chromatography and gel filtration (p.1, method). Ikeura et al. teaches that the lower polarity obtained polyphenol fraction had a 3-fold stronger lipase inhibitory activity and was associated with a higher molecular weight (p.2, result). Ikeura et al. teaches that the higher molecular weight fractions had a higher degree of polymerization (p.2, conclusion). Ikeura et al. also teaches the obtained cocoa, green and oolong tea fractions can be suitable for drinking (p.2, results).

One having ordinary skill in the art would know that the other polyphenols (catechins) with the lower molecular weight fractions inherently have a lower degree of polymerization, since degree of polymerization directly relates to molecular weight. And, one having ordinary skill in the art would expect that the lower molecular weight fraction contains non-polymerized (zero degree of polymerization) polyphenols.

Because Ikeura et al. teaches the highly polymerized polyphenols are suitable for consumption, it is obvious that the polymerized polyphenol is mixed as a composition at a higher concentration relative to non-polymerized polyphenol since it is the high polyphenol with the desired therapeutic properties, i.e. lipase inhibitory activity. Ikeura et al. teaches a composition comprising a higher proportion of polymerized polyphenol relative to non-polymerized polyphenol.

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Consequently, the product lacks a *special technical feature* as defined by PCT Rule 13.2 as it does not possess an inventive step over the teachings of the prior art.

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

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patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. BAHAR SCHMIDTMANN whose telephone number is 571-270-1326. The examiner can normally be reached on Mon-Thurs 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bahar Schmidtmann/
Patent Examiner
Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner
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